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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
03-087 (US01)

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on May 24, 2010

Signature /NancyRushton/

Typed or printed name Nancy Rushton

Application Number	Filed
10/626,246	7/24/03
First Named Inventor	
Christopher J. Elliott	
Art Unit	**Examiner**
3731	Elizabeth Houston

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 37104.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/DavidTBurse/
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Telephone number

May 24, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Christopher J. Elliott	**Confirmation No.:** 1009
Serial No.: 10/626,246	**Group Art Unit:** 3731
Filed: July 24, 2003	**Examiner:** Houston, Elizabeth
For: Embolic Coil	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop: **AF**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request a pre-appeal brief conference. No amendments are being filed with this request. Claims 1, 2, 6-12, 24 and 26-29 remain pending in this application. Claims 1, 2, 6-10, 24 and 26 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over U.S. Patent No. 5,980,514 ("Kupiecki") in view of U.S. Patent No. 5,382,260 ("Dormandy"). Claims 11, 12 and 27-29 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Kupiecki in view of Dormandy, in further view of U.S. Patent No. 6,171,326 ("Ferrera").

Independent claim 1 recites an embolic coil comprising "an elongated core element formed of a shape memory material and movable between a straightened first configuration and a shape memorized second coiled configuration; an elongated outer element which, in the first configuration, is wound around the elongated core element to form a primary coil; and ***a plurality of fibers frictionally gripped between adjacent coils of the primary coil***." (Emphasis added). Claims 2-12 depend from claim 1, and thus include these same limitations. Independent claim 24 similarly recites a coiled medical device comprising a primary coil having a primary coil shape, and a secondary coil formed of a shape memory material and disposed in a lumen extending through the primary coil, the secondary coil having a secondary coil memorized shape, the device further comprising "***a plurality of fibers gripped between adjacent coils of the primary***

coil and held therebetween by friction." (Emphasis added). Claim 26 depends from claim 24, and thus includes these same limitations. An explanation of the claimed frictional fiber retention aspects of the devices of claims 1 and 24 is set forth in paragraphs 16 and 17 of the specification:

[0016] FIG. 4 shows an exemplary embodiment of fibers 22 being attached to the primary coil 54 of an embolic coil. As indicated above, the fibers 22 may be polymeric fibers or may be made of other flexible materials, for example, Nitinol. The fibers 22 are added to the platinum primary coil 54 to impart greater thrombogenicity to the overall embolic coil, and to increase its ability to stop the undesired flow of blood therethrough. **The fibers 22 are generally inserted between the loops 56 of the primary coil 54, and are held in place by virtue of the cold work imparted to the platinum wire during the primary coil winding process.** In an exemplary embodiment, the insertion of the fibers 22 in the loops 56 is carried out after the heat treatment used to set and maintain the shape of the secondary coil 62.

[0017] However, other processes may be better suited to forming embolic coils having enhanced shape retention and fiber retention properties. **Specifically, the retention of the fibers 22 between the loops 56 of the primary coil 54 is a function of the amount of cold work that has been performed and that continues to affect the platinum wire 50. In other words, the fibers 22 remain in place more securely when a large amount of cold work is performed that is not later removed.** ***

(Emphasis added).

Independent claim 27 recites an embolic coil comprising "an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape, the elongated core including a plurality of fiber retention grooves formed in an outer surface thereof; an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and a ***plurality of fibers held within the first fiber retention grooves***." (Emphasis added). Claims 28 and 29 depend from claim 27, and thus includes these same limitations. An explanation of the claimed frictional fiber retention aspects of the device of claim 27 is set forth in paragraph 28 of the specification (with reference to Figs. 7 and 8):

[0028] Additional enhancements may be made to the embolic coil according to the present invention, to improve the device's fiber retention properties. For example, as shown in FIG. 7, the shape memory core wire 120 may comprise cylindrical grooves 124 that are used as anchors for fibers. Grooves 124 channel the fiber bundles around core wire 120, so that they are held in place by the core wire 120. In this manner the primary coil 108 is freed from that function. Channeling the fiber bundles via grooves 124 promotes cohesion of the fibers, and reduced the loss of fibers during use of the embolic coil. In a different embodiment shown in FIG. 8, a shape memory core wire 122 may comprise spiral grooves 126, which also help anchor fibers such as the fibers 22 shown in FIG. 4. In these embodiments, the amount of

cold work imparted to the primary coil 108 has less effect on how well the fibers 22 are retained, and fewer restrictions are imposed on the shape and properties of the primary coil 108.

The Examiner has correctly stated that Kupiecki does not teach or suggest the attachment of fibers to the coil device be any means, and cites Dormandy in support of the rejection. However, Dormandy does not teach that the fibers are "frictionally gripped between adjacent coils of the primary coil," as recited in claim 1, or "gripped between adjacent coils of the primary coil and held therebetween by friction," as recited in claim 24, but instead that the fibers (22) are wound around turns of the coil, and held in place by a loop (23) formed by the winding. (*See* Dormandy, col. 3, lines 50-60, "loop 23 serves as the sole means for retaining the group 21 of fibers 22 on the coil 12."). This is clearly shown in Figs. 3 and 4 of Dormandy:

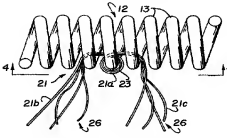


FIG.3

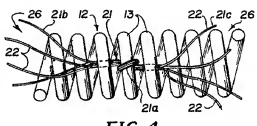


FIG. 4

It is respectfully submitted that the fibers (22) of Dormandy are not frictionally gripped between adjacent coils of the coil (12), especially in light of the fact that adjacent turns of the coil (12) are shown to be spaced from one another. Nor does Dormandy teach or suggest that adjacent turns of the coil (12) are wound tightly against one another. Moreover, the modification of Kupiecki proposed by the Examiner provides unexpected results. Dormandy teaches fibers (22) that are wound around turns of the coil (12) to form a loop (23) by inserting a first free end of the fiber (22) between two turns of a coil and into a cavity located within the coil (12) and the free end is then looped around a turn of the coil and inserted back into the cavity before being drawn out of the coil (12) one last time. It is unclear how incorporating the fibers (22) of Dormandy into the coil device of Kupiecki would result in the device of independent claims 1 or 24, since the fibers (22) of Dormandy cannot be looped around the wire (202) of Kupiecki due to obstruction by the inner core member (204). (*See* Kupiecki, col. 14, ll. 3 - 45; Fig.8).

In order to achieve the desired helical shape, to the wire (202) of Kupiecki must be wound in a tight configuration over the inner core member (204) as a loose winding is incapable of imparting the desired coiled shape. However, Kupiecki states that the wire (202) is secured to the outer body of the inner core member (204) by welding the contacting ends thereof together, thus confirming that the wire (202) is wound tightly over the inner core member (204) so that the resulting coil is held in a contacting configuration therewith. (*Id.* at col. 14, ll. 26 - 32). Thus, the modification proposed by the Examiner would not result in the claimed invention, and it is respectfully submitted that neither Kupiecki nor Dormandy, taken either alone or in combination, disclose or suggest an embolic coil comprising a plurality of fibers that are "frictionally gripped between adjacent coils of the primary coil," as recited in claim 1, or "gripped between adjacent coils of the primary coil and held therebetween by friction," as recited in claim 24. According, it is respectfully requested that the rejection of claims 1, 2, 6-10, 24 and 26 over Kupiecki, in view of Dormandy, be withdrawn.

Regarding claims 11 and 12 (which depend from claim 1), it is respectfully submitted that Ferrera also does not disclose or suggest an embolic coil having a plurality of fibers that are "frictionally gripped between adjacent coils of the primary coil." According, it is respectfully requested that the rejection of claims 1, 2, 6-10, 24 and 26 over Kupiecki, in view of Dormandy, and in further view of Ferrera, be withdrawn.

Regarding claims 27-29, it is further respectfully submitted that Ferrera does not disclose or suggest an embolic coil comprising "an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape, the elongated core including ***a plurality of fiber retention grooves formed in an outer surface thereof***; an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and a ***plurality of fibers held within the first fiber retention grooves***." (Emphasis added).

The Examiner states that "the resultant combination of Ferrera's multi-stranded cable with the base [Kupiecki] device provides fiber retention grooves as claimed (Note the circumferential and spiral grooves formed between each strand in Fig. 4, as well as the circumferential and spiral groove formed by the wrapped cover (56) in Figs. 10a and 10b)." However, it can be plainly seen in the referenced figures of Ferrera that the spaces

between the cables do **not** comprise a plurality of fiber retention grooves formed in an outer surface of an elongated core element, as required by independent claim 27:

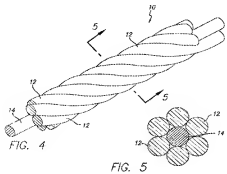
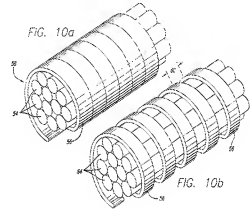


FIG. 4

FIG. 5



Respectfully submitted,
VISTA IP LAW GROUP LLP

Dated: May 24, 2010

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